

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested. Claims 15-19, 21 and 23-25 are pending, with claims 1 being the independent claim. Claim 1 has been amended and claims 20, 22 and 26-28 have been canceled without disclaimer of or prejudice to the subject matter thereof. No new matter has been added by virtue of the amendment to Claim 1.

35 U.S.C. §112 Rejection

Claims 15 and 26 have been rejected under 35 U.S.C. 112, first paragraph. Applicants have amended Claim 1 to remove the language “at room temperature,” thereby rendering the rejection moot. As previously noted, Claim 26 has been canceled.

35 U.S.C. §103 Rejections

All the claims have been rejected under 35 U.S.C. 103. Without acquiescing to the Examiner’s grounds of rejection Applicants have amended independent Claim 1 to now state that the coating is a durable hydrophilic biocompatible coating for a medical device, and to incorporate the limitations of previous claims 20 and 22 therein.

To maintain a proper rejection under 35 USC § 103, the Examiner must meet four conditions to establish a *prima facie* case of obviousness. First, the Examiner must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Examiner must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Examiner must show a suggestion, teaching, or motivation to combine the prior art references (“the TSM test”). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int’l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art.” *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

Claims 15-28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Garnett et al. for the reasons of record. Applicants respectfully traverse. Applicants maintain and repeat their previous arguments of record. Furthermore, Applicants now submit that Claim 1, as amended (and all the dependent claims, which contain all the limitations of Claim 1 and add further limitations) is patentable over Garnett. It is maintained that Garnett does not teach:

A durable hydrophilic biocompatible coating formulation for a medical device having abstractable hydrogen radicals, the formulation including a hydrophilic polymeric component comprising at least two polymeric species of differing molecular weights, an unsaturated hydrophilic monomer capable of free-radical polymerisation in the presence of a radical and a UV activatable compound capable of abstracting hydrogen radicals from the surface to be coated and from a polymeric specie of the hydrophilic polymeric component so as to initiate and promote the cross-linkage of the monomer to the surface and of the monomer or a propagating monomer chain to a polymeric specie of the polymeric component, and a suitable solvent, ~~and~~ wherein said formulation is suitable for coating on an implantable biomedical device with only one curing step, wherein at least one polymeric species comprises a relatively lower molecular weight polymer and at least one polymeric species comprises a relatively higher molecular weight polymer, and wherein the ratio of lower molecular weight polymer to higher molecular weight polymer is between about 1:3 and 1:2.

At most Garnett teaches radiation curable coatings comprising an unsaturated monomer and a mixture of an unsaturated prepolymer and a binder. While molecular weight ranges for the prepolymer and binder are generally provided, they do not distinguish between that for prepolymer and that for binder, except for a very generally statement that “binder polymers are generally of higher molecular weight than prepolymers” and the ranges given are the same for both, 2,000-200,000. In contrast thereto, the ranges in amended Claim 1 do not overlap. Further, Garnett provides no guidance as to ratios of prepolymer and binder polymer. Inasmuch as Garnett is not directed to providing a durable hydrophilic biocompatible coating for a medical device, undue experimentation would be required and there would be no reasonable expectation

of success to arrive at the coatings of the present invention. Accordingly, Applicants submit that the current claims are patentable over Garnett.

Claims 15-28 have been rejected under 35 U.S.C. 103(a) over WO 02/48202 A1. Applicants respectfully traverse.

WO-202 discloses photopolymerizable compositions comprising (A) at least one ethylenically unsaturated free-radical-photopolymerizable compound; (B) at least one surface-active photoinitiator and (C) at least one thermally crosslinkable compound. It is also stated on page 16 that the unsaturated compounds (A) may be low molecular weight (monomeric) or higher molecular weight (oligomeric). Applicants' claims require that there be two polymeric compounds; one of them cannot be monomeric. Further, the cited reference does not specifically disclose or suggest that there be a combination of both lower molecular weight and higher molecular weight polymeric components, and provides no guidance as to the molecular weight ranges. Further, the reference neither teaches nor suggests that compound A can serve three separate and distinct purposes, i.e. be the monomer and both lower and higher molecular weight polymers of the present invention. Accordingly, Applicants submit that the current claims are patentable over WO-202

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,
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